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BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Application Number: 09/737,185
Filing Date: December 14, 2000
Appellant(s): BOWMAN ET AL.

Howard A. MacCord, Jr.
For Appellant

SUPPLEMENTAL EXAMINER'S ANSWER

This is in response to the third supplemental appeal brief filed 03/31/08 appealing from the Office action mailed 01/10/06.

(1) Real Party in Interest

A statement identifying by name the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

(3) Status of Claims

The statement of the status of claims contained in the brief is correct.

(4) Status of Amendments After Final

No amendment after final has been filed.

(5) Summary of Claimed Subject Matter

The summary of claimed subject matter contained in the brief is correct in part. See Notice of Non-Compliance from 04/21/08, which indicates that "Figure 4 referred to in the Summary does not show the "vessel distribution facility" recited in independent claims; the "vessel distribution facility" should be shown either on drawings or in the specification." According to the Petition Decision granted on 06/02/08 "with respect to the first issue, as stated in MPEP 1207.02 and form paragraph 12.153.02, if the examiner disagrees with applicant's summary of the claimed subject matter (as is the case here), the examiner should simply explain the alleged deficiency in the answer and include a correction, rather than holding the brief non-compliant." The examiner cannot correct the Summary, since the expression "the vessel distribution facility" cannot be mapped in the specification. If this definition had any patentable weight in the claims, an issue of new matter could have been raised in the previous Office actions.

(6) Grounds of Rejection to be Reviewed on Appeal

The appellant's statement of the grounds of rejection to be reviewed on appeal is correct, except for claim 44. The examiner withdraws rejection of claim 21 as being obvious over Berney and sustains rejection of claim 21 under 102(b) as being anticipated by Berney.

NEW GROUND(S) OF REJECTION

Claim 44 is rejected under 35 U.S.C. 103(a) as being unpatentable over Petrick or Berney in view of Hoffman et al. (US 5,613,012) or Fukuzaki (US 5,948,103), rather than as being anticipated by Petrick under 35 U.S.C. 102(e) or Berney under 35 U.S.C. 102(b),

as was established in the Office action from 01/10/06. Including claim 44 into anticipatory rejection along with other claims in the Office action from 01/10/06 was an obvious typo on the examiner's site, since the claim comprises a limitation of the electronic signature of the specimen donor, which has been separately recited in several dependent claims and which was recognized by the examiner by a separate rejection of these dependent claims over Petrick or Berney in view of Hoffman et al. (US 5,613,012) or Fukuzaki (US 5,948,103).

(7) Claims Appendix

The copy of the appealed claims contained in the Appendix to the brief is correct.

(8) Evidence Relied Upon

6,535,129	PETRICK	3-2003
5,777,303	BERNEY	7-1998
5,314,421	LEUENBERGER	5-1994
5,613,012	HOFFMAN et al.	3-1997
5,948,103	FUKUZAKI	9-1999
EP 1,004,359 A2	STEVENS et al.	5-2000
5,135,313	BOWMAN	4-1992
RD 421048 A	ANONYM	5-1999

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

Claims 1-21 and 40-44 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

All independent claims recite "a diagnostic specimen system comprising a population of biomedical specimen collection vessels" with the members of the population located in three different locations (a vessel distribution facility, a specimen collection facility, and a specimen testing laboratory). According to 35 U.S.C. 101, patentable inventions are related to "any new and useful process, machine, manufacture, or composition". The collection vessels are the manufacture. However, it is not clear, which category of four listed in 35 U.S.C. 101, "a diagnostic specimen system comprising a population of biomedical specimen collection vessels, located in three different locations", belongs to. Also, "the subject matter of a properly construed claim is defined by the terms that limit its scope. It is this subject matter that must be examined. As a general matter, the grammar and intended meaning of terms used in a claim will dictate whether the language limits the claim scope. *Language that suggests or makes optional but does not require steps to be performed or does not limit a claim to a* ***particular structure*** *does not limit the scope of a claim or claim limitation*." (MPEP, Chapter paragraph §2106). It is not apparent, what particular structure of the diagnostic specimen system is recited in the claims, besides a particular structure recited for collection vessels. Location of a group of identical vessels at a specific place cannot be considered "a particular structure" of the diagnostic system. Moreover, it is not clear, what will happen to the subject matter of the claim, if a part of the system, after being located at the specific location for some time, will be on the way to a different location (e.g. disposal), or on the way from the manufacturing site. Also, it is not clear, if the diagnostic system manufactured at the manufacturing site and still located at that site belongs to the claimed subject matter of the instant application. Furthermore, it is not clear, if the same vessels should always be present at these particular locations, or these vessels are moving from one place to another? If the vessels are moving and changing their location, then how can such system be definite? Besides that, the vessel distribution facility (shelves with the vessels), the specimen collection facility (a special restricted area in the laboratory) and the specimen testing laboratory can be the same place.

The examiner concludes that since the location of the vessels does not further limit their structure, the only subject matter recited in the pending claims which bears patentable weight is related to structure of biomedical (toxicological) vessels, rather than their locations. Moreover, as it was indicated above, all three "facilities" can be located in the same room: a bench with the

vessels comprising tags being "a distribution facility", a special place for collecting samples, e.g. a restroom, being "a specimen collection facility", and a specimen testing laboratory being a lab in the same room. These definitions meet requirements for all claims except for claim 18.

Claim 18 is indefinite as to which data are stored at the vessel distribution facility.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-4, 6-7, 9-12, 14-15, 19, 21, 38 and 40-41 are rejected under 35 U.S.C. 102(e) as being anticipated by Petrick (US 6,535,129 B1).

Petrick discloses a method and a business form attached to a collection vessel for establishing a chain of custody; the invention comprises using a population of biomedical specimen (including toxicology specimen) collection vessels, each having wireless electronic memory tag 106 attached to the vessel for non-contact storage and retrieval of information; the tag includes a radio frequency transponder and stores identification code for the vessel (col. 3, lines 18-36), as well as the information corresponding to the various forms 102: "in one example embodiment, RFID logger 108 may prompt the collection (or other) custodian 54 to input additional required information either manually (e.g., by writing the information onto form 102 using a pen or pencil) and/or **automatically (e.g., by inputting information into a computer workstation or other electronic device via a keyboard, barcode scanner, optical character reader, speech recognition device and/or other data input means) (block 206)**. This additional information may become part of form 102 and/or a data record 110 that RFID logger 108 (and/or chip 106) records. RFID logger 108 may record the collected information onto form 102 and/or in an associated data record 110 (block 208)--which data record is associated with the

particular RFID chip 106" (col. 3, lines 66-67 and col. 4, lines 1-12). Several types of forms are disclosed, which include information on a donor, a specimen and lab work required for the specimen, which all may be entered both manually and electronically. The specimen system further includes a label imprinted with a bar code attached to each vessel, the bar code identifying the vessel (the label of US 5,976,014 recited by Petrick in col. 1, line 60 and col. 3, line 10), the label also serving as a tamper-indicating seal. The information is shared between different remote users: "as shown in FIG. 1, one interesting capability provided by system 50 is the ability to exchange data records 110 between custodian sites. For example, each RFID logger 108 may be coupled to the Internet, an enterprise intranet, a local or wide area network, the telephone network, or other data network 112. Data network 112 allows the various data loggers 108 to share automatically collected information and/or record the collected information to a centralized or distributed database facility 114 for archival and management purposes. Data network 112 allows data records 110 associated with an RFID chip 106 to "follow" the RFID chip in the sense that any node connected to the network may (if authorized) access a record tagged to the RFID chip" (col. 4, lines 45-57). The method for recording information includes providing a population of biomedical specimen containers, which a collection custodian receives from a distribution location (see Figure 1), collecting a specimen from a donor in the specimen container at the specimen collection facility and electronically storing information about the specimen, donor, and/or test to be performed in the specimen on the electronic memory tag (col. 3 and 4).

Claims 1, 6-7, 9, 14-15, 19, 21 and 40-41 are rejected under 35 U.S.C. 102(b) as being anticipated by Berney (US 5,777,303).

Berney discloses a diagnostic specimen system comprising a plurality of biomedical specimen collection vessels (test tubes) and a wireless electronic memory tag for non-contact storage and retrieval of information (Abstract, Figure 5). "FIG. 5 shows an exemplary configuration of an electronic label 50 being accessible via radiofrequencies (RF) and which can be used within the scope of the invention. As distinct from the preceding figures, which described devices using labels with contacts, it is of course also possible to use other kinds of electronic labels, **especially labels being read from distance**. This is the case for radiofrequency labels, which use a magnetic coupling" (col. 3, lines 26-33). "Said electronic

label 4 allows a registration of all useful information required for said analysis, in particular, information relating to the person under concern, to basis reference data, to the analysis data and to the result data, to the used analysis apparatus, to the service staff, etc." (col. 1, lines 61-67, col. 2, lines 1-2). "FIG. 4 shows an exemplary embodiment of means for reading/writing of a plurality of test tubes 40, 41, 42, 43 and 44 being equipped with electronic labels mounted on their supports. … It is therefore possible, to control the entirety of the operations relating to the reading and to the transfer of information within the labels under concern with the aid of the keyboard 48 and via computer program menus, allowing to reduce error risks to a minimum. In order to perform, for example, a blood analysis, firstly the reference data of the patient under concern and the kind and number of analyses to be performed are fed directly from a central database into the label. Secondly the date of analysis, the used analysis apparatus, the name of the service operator, the result data, etc are registered. Finally all this information is transferred to the centralized data bank of the patient" (col. 2, lines 66-67 and col. 3, lines 1-25). There are no structural differences between "a diagnostic specimen container" and "a toxicology specimen container" the way they are recited in the claims indicated above.

"A population of "biomedical specimen collection" with "members" located at various locations of the specimen path is an inherent feature of the invention. As soon as the tag becomes attached to the test tube, the location where it occurs becomes "a distribution facility". Attaching the tag with all information should occur before collection of the sample into the vessel. The expression "said labels are mounted on supports being provided to fix said labels onto said test tubes during the time of analysis" obviously refers to analysis in general. The situation, when the tubes are used for collecting samples without providing any information related to the sample and "the person under concern" (col. 1, line 68) seems improbable. The system inherently includes an electronic database accessible from the specimen collection facility for storing data entered at the collection facility. Exchanging information between the collection of vessels and a remote location inherently comprises an electronic network. Berney discloses a method for recording information about a diagnostic specimen by providing a population of biomedical specimen containers with wireless electronic memory tags, distributing these containers to a specimen collection facility, collecting samples and electronically storing information about the specimen, donor, and/or tests to be performed, as it is indicated previously.

Moving the test tubes from the collection facility (a desk where the samples are taken) to the analysis site is what Barney discloses for his population of the test specimen tubes with electronic tags.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 5, 8, 13 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Petrick or Berney in view of the prior art disclosed by Leuenberger (US 5,314,421).

The disclosure of Petrick and Barney is provided above.

Although Petrick or Berney do not specifically disclose storing data including the identity of a supplier of vessels and product information, such information is conventionally provided for all manufactured products, including test tubes (vessels, containers). Also, Leuenberger who discloses blood plastic containers indicates in the "Background of the Invention": "of course, it is necessary to provide some means for identifying certain information on the blood pack, e.g., the type of storage solution, anticoagulant, or blood component, the collection date, *manufacturer's product code* and *lot number*, etc." (col. 1, lines 13-18).

It would have been obvious for anyone of ordinary skills in the art to include information on the product and product supplier in the electronic tag the same way as indicated by Leuenberger for blood packs, because containers from different suppliers may vary, and therefore such information is important for handling containers properly, and also because information on a supplier and the product is always conventionally provided with all manufactured products, especially test tubes (vessels, containers).

It would have been obvious for any person of ordinary skill in the art to store this information before collecting the samples into the vessels. It would have been obvious for any person of ordinary skill in the art to ship members with electronically stored data to the specimen collection facility, because shipping test tubes from a distribution facility to a specimen collection facility with information on manufacturer/supplier and the test tubes is a conventional step in diagnostic environment, and upgrading this system by electronically storing this

information is obvious for Petrick's or Berney's test tubes, which are specifically designed for handling such information.

Claims 16-17, 20 and 42-44 are rejected under 35 U.S.C. 103(a) as being unpatentable over Petrick or Berney in view of Hoffman et al. (US 5,613,012) or Fukuzaki (US 5,948,103).

The disclosure of Petric and Barney is provided above.

Petrick or Berney do not particularly teach encoding electronic signature in the electronic tag, although Petrick specifically indicates "tester's signature" in form 102, Fig. 3B. The signature of the "person under concern" (Berney, col. 1, line 68) is conventional for all forms related to testing biological samples.

Hoffman teaches using an electronic signature (col. 32) in a "tokenless identification system for authorization of electronic transactions and electronic transmissions" (Abstract), with the electronic signature securing electronic transactions.

Fukuzaki discloses an electronic document security system, affixed electronic seal security system and encoded electronic signature security system for securing electronic documents transmitted by electronic means.

It would have been obvious for anyone of ordinary skill in the art to incorporate encoded electronic signature of the type disclosed by Hoffman or Fukuzaki for securing electronic transactions into Petrick's or Berney's system, specifically for the reasons indicated by Hoffman and Fukuzaki, i.e. for securing electronically transferred data, and because the signature of "the person under concern" is conventional in all diagnostic procedures.

Claims 2 and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Berney in view of disclosure of RD 421048 A.

The disclosure of Barney is provided above.

Berney does not specifically disclose a radio frequency transponder, although he mentions that "it is of course also possible to use other kinds of electronic labels, especially labels being read from distance. This is the case for radiofrequency labels".

RD 421048 A discloses a "method for logging, identification, tracking, and chemical management in a chemical synthesis system (CSS) – by applying an electronic identification tag to each container as it passes through the system" (Title). "The identification (ID) tags could be self-powered or passive **transponder** type". "The ID tag with each container individualizes the

solvents, reagents, intermediates and finished compounds within the CSS" (Abstract). "A complete and accurate log of every container transport and access can be maintained. … Chain of custody with ID labeling is excellent" (Advantage).

It would have been obvious for anyone of ordinary skills in the art to use a radio-frequency transponder in the electronic memory tag, disclosed in RD 421048 A, in Berney's specimen container, because transponder gives more flexibility in "logging, identification, tracking and chemical management" of the container due to the long-range action of the transponder, as demonstrated in RD 421048 A and because this is one of "other kinds of electronic labels, especially labels being read from distance", mentioned by Berney.

Claims 3-4 and 11-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Berney in view of Stevens et al. (EP 1,004,359 A2).

The disclosure of barney is provided above.

Berney does not specifically disclose a container, which further includes a label imprinted with an identifying barcode and the electronic tag of which stores data including an identification code for the container.

Stevens discloses a partitioned specimen label for collection containers, which comprises "a machine readable barcode identification and a portion of the label and barcode can be removed from the container and subsequently affixed to test request forms and the like. The label of the present invention is able to create a direct link between the container, the patient and the test request forms" (col. 2, paragraph [0013]). In one of the embodiments, "the first two of the digits [of the barcode] are fixed and identify the tube and product type for features such as but not limited to tube size, tube material and internal additives" (col. 4, l. 58 and col. 5, ll. 1-2).

It would have been obvious for anyone of ordinary skills in the art to improve Berney's container comprising the electronic tag by adding a label with a barcode and providing the same information to the electronic tag in the same way Stevens labeled his container, because this serves the same purpose that Stevens disclosed in his invention, i.e. to "create a link between the container, the patient and the test request forms", or any other forms associated with using this container.

Claim 38 is rejected under 35 U.S.C. 103(a) as being unpatentable over Berney in view of Bowman (US 5,135,313).

The disclosure of Barney is provided above.

Berney does not specifically disclose the vessel with a tamper-indicating seal.

Bowman discloses a chain-of-custody tamper-indicating seal for a bag for sealing a specimen taken to a remote location.

It would have been obvious for anyone of ordinary skill in the art to modify Berney's specimen collection vessel with tamper-indicating seal disclosed by Bowman for the same reasons indicated by Bowman, i.e. "so that any attempted tampering with the specimen will be indicated by at least a partial destruction of the seal" (col. 1, lines 7-8).

Claim 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Berney in view of RD 421048 A, Stevens and Leuenberger.

The disclosure of Barney is provided above.

Berney discloses a diagnostic specimen container comprising a biomedical specimen collection vessel (a test tube) and a wireless electronic memory tag for non-contact storage and retrieval of information (Abstract, Figure 5). "Said electronic label 4 allows a registration of all useful information required for said analysis, in particular, information relating to the person under concern, to basis reference data, to the analysis data and to the result data, to the used analysis apparatus, to the service staff, etc." (col. 1, lines 61-67, col. 2, lines 1-2).

Berney does not specifically disclose a radio frequency transponder, although he mentions that "it is of course also possible to use other kinds of electronic labels, especially labels being read from distance. This is the case for radiofrequency labels".

RD 421048 A discloses a "method for logging, identification, tracking, and chemical management in a chemical synthesis system (CSS) – by applying an electronic identification tag to each container as it passes through the system" (Title). "The identification (ID) tags could be self-powered or passive **transponder** type". "The ID tag with each container individualizes the solvents, reagents, intermediates and finished compounds within the CSS" (Abstract). "A complete and accurate log of every container transport and access can be maintained. … Chain of custody with ID labeling is excellent" (Advantage).

It would have been obvious for anyone of ordinary skills in the art to modify Berney container (test tube) by introducing a radio-frequency transponder in the electronic memory tag, disclosed in RD 421048 A, because transponder gives more flexibility in "logging, identification,

tracking and chemical management" of the container due to the long-range action of the transponder, as demonstrated in RD 421048 A

Berney in view of RD 421048 A do not disclose a container, which further includes a label imprinted with an identifying barcode and the electronic tag of which stores data including an identification code for the container.

Stevens discloses a partitioned specimen label for collection containers, which comprises "a machine readable barcode identification and a portion of the label and barcode can be removed from the container and subsequently affixed to test request forms and the like. The label of the present invention is able to create a direct link between the container, the patient and the test request forms" (col. 2, paragraph [0013]). In one of the embodiments, "the first two of the digits [of the barcode] are fixed and identify the tube and product type for features such as but not limited to tube size, tube material and internal additives" (col. 4, l. 58 and col. 5, ll. 1-2).

It would have been obvious for any person of ordinary skill in the art to add a label with a barcode and provide the same information to the electronic tag in the same way Stevens labeled his container, because this serves the same purpose that Stevens disclosed in his invention, i.e. to "create a link between the container, the patient and the test request forms", or any other forms associated with using this container

Berney in view of RD 421048 A and Stevens do not specifically indicate that the tag contains information on the supplier and the product (container) information.

Leuenberger in his "Background of the Invention" related to the blood pack labels indicates, concerning blood plastic containers, "of course, it is necessary to provide some means for identifying certain information on the blood pack, e.g., the type of storage solution, anticoagulant, or blood component, the collection date, manufacturer's product code and lot number, etc." (col. 1, lines 13-18).

It would have been obvious for any person of ordinary skill in the art to add information on identity of suppliers as indicated by Leuenberger, because this conventional information is always provided with the manufacture products, especially the test containers, and because the identity of the supplier and the vessel may assist in the proper handling the vessel.

Claim 17 is rejected under 35 U.S.C. 103(a) as being unpatentable over Berney in view of RD 421048 A, Stevens, Leuenberger the same way it is applied to claim 8 above, and further in view of Hoffman or Fukuzaki.

Berney in view RD 421048 A, Stevens and Leuenberger do not particularly teach encoding electronic signature in the electronic tag, although the signature of the "person under concern" (Berney, col. 1, line 68) is conventional for all forms related to testing biological samples.

Hoffman teaches using an electronic signature (col. 32) in a "tokenless identification system for authorization of electronic transactions and electronic transmissions" (Abstract), with the electronic signature securing electronic transactions.

Fukuzaki discloses an electronic document security system, affixed electronic seal security system and encoded electronic signature security system for securing electronic documents transmitted by electronic means.

It would have been obvious for anyone of ordinary skill in the art to incorporate encoded electronic signature of the type disclosed by Hoffman or Fukuzaki for securing electronic transactions into Berney- RD 421048 A-Stevens-Leuenberger's system, specifically for the reasons indicated by Hoffman and Fukuzaki, i.e. for securing electronically transferred data, and because the signature of "the person under concern" is conventional in all diagnostic procedures.

(10) Response to Argument

Applicant's arguments filed with the Appeal Brief on 03/31/08 have been fully considered but they are not persuasive.

Rejection of claims 1-21 and 40-44 under 35 U.S.C. 112, second paragraph.

The Appellants obviously misinterpret the examiner's rejection of the pending claims under 35 U.S.C. 112, second paragraph, as "not directed to statutory subject mater". The claims are not rejected under 35 U.S.C. 101 as "not being directed to the statutory subject matter". The examiner rather rejected the claims under 35 U.S.C. 112, second paragraph, as being indefinite and unclear as *to what* the Appellants consider to be the statutory subject matter of the claims. The examiner unambiguously stated that the only statutory subject matter of the claims is a vessel (or a plurality of vessels) with an electronic tag, which belongs to the category

"manufacture". Location of the vessels is not a manufacture and is not a further limitation to the structure of the vessel. It is not quite clear to the examiner, what specifically the Appellants' found "not in accordance with the law" in the examiner's rejection of the pending claims under 35 U.S.C. 112, second paragraph (see page 17 of the Appellants' arguments)? If the Appellants consider "a specimen system having collection vessels in specified locations" a manufacture, as they state on page 17 of their arguments, the examiner cannot agree with this. The only manufacture in this recitation is the vessels themselves. Their location is irrelevant to the statutory subject matter indicated in 35 U.S.C. 101. Thus, since the location of the vessels does not further limit their structure of the vessels, it does not bear any patentable weight in the claim recitation.

Appellants' referring to a frequent recitation of elements in various *positions* (*sic*, the term "position" is not a synonym to the term "location"), which they provide on page 18, is irrelevant to the subject matter of the instant claims. The pending claims do not recite a unified manufacture product comprising interconnected elements, but rather a plurality of identical vessels, which are independent from each other and which can be located anywhere.

The examiner respectfully reminds the Appellants that according to MPEP §2171:

"The second paragraph of 35 U.S.C. 112 is directed to requirements for the claims:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

There are two separate requirements set forth in this paragraph:

(A) the claims must set forth the subject matter that applicants regard as their invention; and

(B) the claims must particularly point out and distinctly define the metes and bounds of the subject matter that will be protected by the patent grant.

The first requirement is a subjective one because it is dependent on what the applicants for a patent regard as their invention. *The second requirement is an objective one because it is not dependent on the views of applicant or any particular individual, but is evaluated in the context of whether the claim is definite — i.e., whether the scope of the claim is clear to a hypothetical person possessing the ordinary level of skill in the pertinent art.*"

The examiner states that the scope of the claims reciting "a diagnostic specimen system comprising a population of biomedical specimen collection vessels located at and transportable between a vessel distribution facility, a specimen collection facility, and a specimen testing laborer" does not meet the requirement B) of the second paragraph of 35 U.S.C. 112. Because

location and transporting a population of biomedical vessels are not related to the structure of the biomedical vessels and are not defined by any metes and bounds of the claim language, the recitation of the claims that is not related to the specific structure of the biomedical vessel fails to meet the requirement of the second paragraph of 35 U.S.C. 112.

Regarding indefiniteness of claim 18, the examiner assumes that if there is a question as to what specifically the examiner needs to search in order to examine the claim, the examiner can raise an issue of unclarity and indefiniteness of the language of the claim. Claim 18 recites "electronically storing data" as one of the elements without indicating, as to which data should be stored on the tag. Since it is unapparent, as to which data the Appellants recite in the claim, which prevents the examiner from the proper search, it appears to be a clear case of unclarity and indefiniteness of the claim. Again, the second paragraph 35 U.S.C. 112 states that "the claims must particularly point out and distinctly define the metes and bounds of the subject matter that will be protected by the patent grant." The step of "electronically storing data on one of the electronic memory tags at the vessel distribution facility" does not "particularly point out and distinctly define the metes and bounds of the subject matter that will be protected by the patent grant", since it is not apparent, as to which data should be stored on the tags.

Rejection of claims 1-4, 6-7, 9-12, 14-15, 19, 21, 38 and 40-41 under 102(e) as being anticipated by Petrick's US 6,535,129.

As the examiner indicated in the previous Office actions, she considers instant invention and Petrick's invention disclosed in US 6,535,129 patentably indistinct. The instant invention claims a collection of vessels with wireless electronic memory tags. Petrick claims a business form comprising a wireless electronic device (tag), which is adhered to the specimen *or to a container containing a specimen* (claim 7). It is a clear anticipatory recitation for claim 1 of the pending application. Location of the vessels is not a patentable subject matter and does not bear any patentable weight, as was indicated previously. "A container" recited by Petrick is obviously "a plurality of containers", with singular and plural forms conventionally inter-changeable in claims recitation. Therefore, the Appellants' claim is not novel in view of the Petrick's claimed invention.

Petrick claims a business form with the wireless identification device adhered to the specimen container, and the Appellants recite vessels with wireless tags and labels with

identification bar code attached to vessels (see e.g. claims 3, 12, etc.). According to the Appellants specification,

> "[a]n electronic memory tag 3 is affixed to an exterior surface of the vessel 1. An enlarged front view of a preferred embodiment of the electronic memory tag 3 is shown in FIG. 2. The electronic memory tag 3 includes a carrier label 4 which has a front face 5 and a rear face 6. Preferably, the front face 5 is imprinted with an identification bar code 7. A text area 8 is also provided for printing, typing, or writing pertinent information on the front face 5 of the carrier label 4. A detail view of the rear face 6 of the carrier label 4 is shown in FIG.3. An electronic memory device 9 is attached to the rear face 6. Alternatively, the invention may include a separate electronic memory tag 3 and a second printed label having a bar code 7 imprinted thereon (not shown)." (page 11).

Thus, the recitation of the Appellants' claims comprises both embodiments, i.e. having electronic tag and a label on a single form and on separate forms, and reads on any of them. The first embodiment is identical to the claimed Petrick's subject matter. Also, having the tags and labels both on the same "business form" or on separate forms would have been an obvious modification for an alternative embodiment, with both type of forms for biological specimen containers notoriously well known in the art. Therefore, Petrick's invention would be either anticipatory for, or an obvious modification of the Appellants' invention. Attachment of the wireless tag to the form (paper) inherently provides a visual indication of "de-associating" the tag from the form, when it occurs. Petrick in claim 7 recites attaching a wireless identification device directly to a specimen "*or a container containing the specimen*", with the second part of the recitation, which the Appellants for some reason forgot to mention.

Regarding the method claims: in claim 8 Petrick recites establishing "chain of custody" using the wireless tag attached to the form and container, with the "chain of custody" for a biological specimen inherently comprising distributing, transferring and analyzing specimen in the containers at corresponding locations. The chain of custody comprises all these elements by definition. Therefore, the recitations of claim 8 of Petrick's patent and that of claim 18 of the instant application are not patentably distinct.

This establishes two-way anticipating and/or obviousness of the instant invention and Petrick's prior art, which makes them patentably indistinct.

Establishing patentable identity for the instant application and Petricks' invention makes the Declaration 1.131 improper in the present case, since according to MPEP § 1.131: "Prior

invention may not be established under this section if … the rejection is based upon a U.S. patent or U.S. patent application publication of a pending or patented application to another or others which claims *the same patentable invention* as defined in § 41.203(a) of this title, in which case an applicant may suggest interference pursuant to § 41.202(a) of this title".

On pages 23-27 the Appellants perform their own two-way comparative analysis of the claimed inventions by Petrick and by the present Appellants.

The first Appellants' statement that the Appellants' claim 1 is novel over Petrick because it claims a population of collection vessels having members at different locations does not seem convincing. First, as it has been indicated by the examiner above, a population of collection vessels having members at different locations is patentably indistinct from one collection vessel that has exactly the same structure as the plurality of the population vessels. Second, Petrick's subject matter related to the business form comprising an electronic tag and attached to the vessel inherently comprises a plurality of such business forms attached to a plurality of vessels and located at different locations for the following reason. The subject matter of the Petrick's claimed invention is related to "establishing a chain of custody", as recited in claim 8. "The chain of custody" refers to handling a plurality of biomedical samples along the chain of custody, which inherently assumes handling a plurality of the biomedical containers located at corresponding locations along the "chain of custody". Thus, Petrick's *claimed* subject matter is not patentably distinct from the Appellants' claimed subject matter.

As for the statement that "Appellants' claims is not even directed to similar subject matter", it appears that the Appellants cited the first three words from each claim to show a difference in the subject matter of the claimed inventions. The examiner does not consider this as a proper argumentation. As for the Petrick's electronic tag being attached to the form *vs*. the Appellants' electronic tag being attached to the vessel, the exact recitation of the Appellants' claim is the following, "wherein each of the collection vessels includes a wireless electronic memory tag for non-contact storage and retrieval of information ... such that the tag remains attached to the vessel". No claims recite "direct" attachment of the tag to the vessel. Furthermore, according to the Appellants specification,

> "[a]n electronic memory tag 3 is affixed to an exterior surface of the vessel 1. An enlarged front view of a preferred embodiment of the electronic memory tag 3 is shown in FIG. 2. The

> electronic memory tag 3 includes a carrier label 4 which has a front face 5 and a rear face 6. Preferably, the front face 5 is imprinted with an identification bar code 7. A text area 8 is also provided for printing, typing, or writing pertinent information on the front face 5 of the carrier label 4. A detail view of the rear face 6 of the carrier label 4 is shown in FIG.3. An electronic memory device 9 is attached to the rear face 6. Alternatively, the invention may include a separate electronic memory tag 3 and a second printed label having a bar code 7 imprinted thereon (not shown)." (page 11).

Thus, the recitation of the Appellants' claims comprises both embodiments, and reads on any of them, with the first embodiment totally identical to the claimed Petrick's subject matter.

As for the "vessel distribution facility", again, as soon as the tag is attached to the vessel, the location becomes the "vessel distribution facility".

As for the Appellants' analysis of the Appellants' claimed subject matter as the prior art to Petrick's claimed subject matter, the Appellants disclose in their specification two embodiments for the form comprising either two separate parts, one for the electronic tag and another one for providing other relevant information, or one part with the electronic tag attached to the form. Both embodiments read on the Appellants' claimed subject mater, with one of these embodiments being exactly the same as the subject matter claimed by Petrick. Nowhere do the Appellants recite an electronic tag *directly* attached to the vessel. Furthermore, according to MPEP §2111,

> "the pending claims must be "given their broadest reasonable interpretation consistent with the specification." >The Federal Circuit's *en banc* decision in *Phillips v. AWH Corp.*, 415 F.3d 1303, 75 USPQ2d 1321 (Fed. Cir. 2005) expressly recognized that the USPTO employs the "broadest reasonable interpretation" standard:
> The Patent and Trademark Office ("PTO") determines the scope of claims in patent applications not solely on the basis of the claim language, but upon giving claims their broadest reasonable construction "in light of the specification as it would be interpreted by one of ordinary skill in the art." *In re Am. Acad. of Sci. Tech. Ctr.*, 367 F.3d 1359, 1364[, 70 USPQ2d 1827] (Fed. Cir. 2004). Indeed, the rules of the PTO require that application claims must "conform to the invention as set forth in the remainder of the specification and the terms and phrases used in the claims must find clear support or antecedent basis in the description so that the meaning of the terms in the claims may be ascertainable by reference to the description." 37 CFR 1.75(d)(1)".

In view of such approach to the claim analysis, the examiner interprets the Appellants' claims as reciting an electronic tag attached to the business form, rather than directly to the vessel, because this is exactly how this is disclosed in the specification, although no particular business form is recited in the claims.

Therefore, the two-way claim analysis performed by the examiner meets the requirements established in *Winter vs. Fujita*.

The examiner believes that the further Appellants' analysis of the recited method in Petrick and in the instant application follows the same path as the one used for the apparatus claims. The examiner would like to indicate again, that as soon as Partrick's electronic tag becomes attached to the vessel, with the electronic tag containing any information (since the information is not specified in claim 18 of the instant application), the vessel becomes located in the "vessel distribution location". The "chain of custody" assumes transferring vessels between different locations of the chain, with corresponding information added to the tags.

Regarding different classification of the instant application and Petrick's patent, as the examiner indicated in the previous Office actions, "the Applicants' statement that just a mere classification of inventions in different classes unambiguously indicates that they are patentably distinct, is not quite correct, which is confirmed by the Applicants' own application. While it contains two separate groups of claims directed to a specimen system and a method for recording information, classified in different classes, they are not patentably distinct, and therefore were not restricted". Classification of the inventions in different classes is never a mere basis for restriction requirements, contrary to the Appellants' statement. It is only a patentable distinction between different inventions, which makes the proper basis for the restriction requirements.

Regarding Illuminated Examiner's Errors, the examiner believes that the Appellants misinterpreted several of the examiner's statements. It is not quite clear, as to which grounds the Appellants used to conclude that the following was the examiner's statement "[i]t appears that there is no case when the applicant's and Petricks' inventions can be the same"? It appears that the Appellants extracted an excerpt from the examiner's arguments, thus totally distorting their meaning, which the examiner believes not a proper response to the examiner's arguments.

What the examiner said on page 13 of the Office action from 01/10/06 was related to unclarity of the Appellants' analysis of patentability relation between Petrick's and instant inventions:

> "Further, in their arguments related to comparing their invention with the one of Petrick, the Applicants make a statement that the examiner does not quite understand. On page 10 of the Appeal Brief the Applicants state: "*If Applicant's claim is new and non-obvious in view of Petrick's claim, the claims describe separate patentable inventions. If not, the parties are not claiming the same patentable invention*". It appears that there is no case when the Applicants' and

> Petrick's inventions can be the same. Contrary to this statement, the examiner indicates that the inventions are the same ...".

Thus, the phrase "*It appears that there is no case when the Applicants' and Petrick's inventions can be the same"* was not the examiner's statement. It was rather a rhetoric question followed from the Appellants analysis of the relation between the Appellants' and Petrick's inventions, which did not leave a possibility for the inventions to be the same. The examiner did not agree with this conclusion, as the examiner clearly stated in the same paragraph, contrary to the Appellants' remarks.

As for the indication that tampering Petrick's form would have been visually observable, the same can be said about Appellants' forms. Nothing indicates in the Appellants' claims that tampering electronic tag would not have left any noticeable traces, although this is not expressly recited in the claims.

The Appellants further continue arguing that location of the vessels has patentable weight. The examiner has already expressed her opinion on this statement. If location had any patentable weight, then e.g. NMR spectrometer located in e.g. Washington, DC, would have been patentably distinct from the same NMR spectrometer located in e.g. California.

Regarding considering the claims in light of the specification, the examiner has already indicated that it is the way the claims are supposed to be interpreted according to MPEP. It is not quire apparent, as to where the examiner "wholesale imports limitations from the specification into the claims". Which specific limitations the Appellants refer to?

As to the lack of examiner's efforts to show different locations for Petrick's vessels with the business forms, it appears that the examiner has fully demonstrated that the whole idea of the "chain of custody" is based on transferring a plurality of the vessels with attached business forms comprising electronic tags between different locations related to transferring biomedical samples.

As to the Appellants' conclusion that the "Applicant should be entitled to provoke an interference", the examiner fully agrees with this. However, it does not seem that the Appellants took this path, and no interference has been provoked in the instant case.

As to the invalidity of the Declaration under 1.131, in fact according to MPEP §715.05:

"715.05 [R-5] U.S. Patent or Application Publication Claiming Same Invention:

> When the reference in question is a noncommonly owned U.S. patent or patent application publication claiming the same invention as applicant and its publication date is less than 1 year prior to the presentation of claims to that invention in the application being examined, applicant's remedy, if any, must be by way of 37 CFR 41.202 instead of 37 CFR 1.131. If the reference is claiming the same invention as the application and its publication date is less than 1 year prior to the presentation of claims to that invention in the application, this fact should be noted in the Office action. The reference can then be overcome only by way of interference. See MPEP Chapter 2300. If the reference is a U.S. patent which claims the same invention as the application and its issue date is more than 1 year prior to the presentation of claims to that invention in the application, a rejection of the claims of the application under 35 U.S.C. 135(b)(1) should be made."

Rejection of the pending claims as being anticipatory over Berney (page 31 of the Appeal Brief).

The discussion of the prior art of Berney starts on page 35 (with the title provided on page 31). The major focus of the Appellants' discussion of the Berney's disclosure is that Berney's electronic tag is attached to the vessel during the analysis and is temporary. First, the tag cannot be attached *during* the analysis, since during the analysis the vessel with the biological sample is in use. Furthermore, the electronic tag bears information on the patient and the tests to be done with the sample, which means that the information should be written into the tag as soon as the vessel receives the sample. As soon as the vessel receives the tag attached to the vessel, the location of the vessel becomes "the vessel distribution facility". The fact that the spring-loaded mount is removable does not mean that it is removed, the same way as the label used by the Appellants can be removably attached to the vessel, which does not mean that it will be removed.

As for such limitations as vessel locations, the examiner already expressed her view on the patentability weight of such claims limitations, not mentioning that all these locations are inherent for all custody chains of medical samples.

Even if the Berney's tags were attached in the lab, the bench in the lab on which the vessels with attached tags are located is the "vessel distribution facility", the vessels are transferred to the table (collection site) and into the analyzer (analysis site). Thus, Berney's reference is anticipatory for claim 21, rather than obvious. The examiner withdraws obviousness rejection of claim 21 over Berney in the present Examiner's Answer.

Claim 44 is rejected as being obvious over both Petrick and Berney for the reason indicated above.

It appears from the Appellants' arguments related to all dependent claims rejected under obviousness-type rejection, that the major statement of the Appellants is that Petrick and Berney is not the prior art for the pending claims, which were rejected over Petrick and Berney on anticipatory basis. It also appears that the Appellants' refer to the secondary references as lacking all limitations of the independent claims rejected over Petrick and Berney on anticipatory basis, which is not a proper way of arguing obviousness type rejections. It does not appear that the Appellants have any additional arguments regarding obviousness type rejections.

In particular, it is not clear, where the Appellants found the following expression in the examiner's Office action: "[t]o conclude that it would have been obvious to transport Berney's vessels because transporting the vessels allows tracking the vessels, as the Examiner did, does not address the issue whether one of ordinary skill would have modified Berney to produce Appellant's invention." Such statement assigned to the examiner does not make much sense, and it is not quite clear, as to where the Appellants have found it.

Regarding combination of Petrick's or Berney's teachings of using electronic tags for storing electronic information and Leuenberger's teaching of disclosing information on manufacturers and products, it would have been obvious for any routineer in the art to store information disclosed by Leuenberger in Petrick's or Berney's electronic tags for an obvious reason of improving storing information in electronic tags *vs*. paper forms.

Rejection of claim 8 does not seem to be properly analyzed, since the examiner has used multiple references for the claim rejection, which were not even considered by the Appellants in their arguments.

Regarding claims 3-4 and 11-12 the Appellants remark that it would not have been obvious for any person of ordinary skill in the art to use Stevens' label, because it disturbs Barney's invention of eliminating all manual entry to the form. The examiner considers these arguments not persuasive for the following reasons: first, Barney did not mention anywhere that "all" useful information should be written in the electronic tags, and, second, such label secures the identity of the vessel in the case when, e.g. the tag is lost, which would have been obvious for any routineer in the art.

As for modification of Barney's tube with the tamper-indicating seal, disclosed by Bowman (Claim 38), such protection is necessary even when the samples are left in the same facility, since tampering is possible not only during transferring tubes with samples between facilities, but when they are stored at the same place.

The examiner believes that she responded to all Appellants' arguments, with motivations for all combinations of the prior art used by the examiner in the basis for obviousness rejections, clearly expressed in the examiner's Office action and repeated in the present Examiner's Answer.

(11) Related Proceeding(s) Appendix

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

For the above reasons, it is believed that the rejections should be sustained.

This examiner's answer contains a new ground of rejection set forth in section **(9)** above. Accordingly, appellant must within **TWO MONTHS** from the date of this answer exercise one of the following two options to avoid *sua sponte* **dismissal of the appeal** as to the claims subject to the new ground of rejection:

(1) **Reopen prosecution.** Request that prosecution be reopened before the primary examiner by filing a reply under 37 CFR 1.111 with or without amendment, affidavit or other evidence. Any amendment, affidavit or other evidence must be relevant to the new grounds of rejection. A request that complies with 37 CFR 41.39(b)(1) will be entered and considered. Any request that prosecution be reopened will be treated as a request to withdraw the appeal.

(2) **Maintain appeal.** Request that the appeal be maintained by filing a reply brief as set forth in 37 CFR 41.41. Such a reply brief must address each new ground of rejection as set forth in 37 CFR 41.37(c)(1)(vii) and should be in compliance with the other requirements of 37 CFR 41.37(c). If a reply brief filed pursuant to 37 CFR 41.39(b)(2) is accompanied by any amendment, affidavit or other evidence, it shall be treated as a request that prosecution be reopened before the primary examiner under 37 CFR 41.39(b)(1).

Extensions of time under 37 CFR 1.136(a) are not applicable to the TWO MONTH time period set forth above. See 37 CFR 1.136(b) for extensions of time to reply for patent

applications and 37 CFR 1.550(c) for extensions of time to reply for ex parte reexamination proceedings.

Respectfully submitted,

Yelena G. Gakh /Yelena G. Gakh/

A Technology Center Director or designee must personally approve the new ground(s) of rejection set forth in section (9) above by signing below:

/Gregory L Mills/
Supervisory Patent Examiner, Art Unit 1700

Conferees:

/Jill Warden/
Supervisory Patent Examiner, Art Unit 1797

Patrick J. Ryan

/PATRICK RYAN/
Supervisory Patent Examiner, Art Unit 1795

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